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RX News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bndd/index.php

Termination of COVID State of Emergency Waivers

The temporary waivers that were in place due to the COVID State of Emergency ended December 31, 2021. All statutes and regulations regarding controlled substance activities are in full effect, with no allowance for any further exceptions, exemptions or waivers.

COVID Waiver Ends - - Electronic Prescribing Now Mandatory

Section 195.550, RSMo requires all controlled substance prescriptions be issued via electronic prescribing. There are approximately eight exceptions to electronic prescribing that are listed in the statute. The implementation of this law was delayed due to the state of emergency. Now the state of emergency has ended, the requirement for electronic prescribing is in full effect. For more complete information, visit the BNDD website at https://health.mo.gov/safety/bndd and click on the link to Electronic Prescribing at the top of the BNDD homepage. Practitioners who are seeking a waiver may fill out the application provided and email it to the specific email address provided on the application. The waivers can be authorized according to the reasons listed in the statute and these waivers are not related to COVID issues.

US Drug Enforcement Administration Update

As of January 2022 -

The US Drug Enforcement Administration (DEA) continues to have waivers in place regarding telemedicine. It is not known how long these waivers will be in place. Practitioners may visit the DEA website at www.deadiversion.usdoj.gov to review current COVID waivers.

The DEA has a statute in place that requires patients to be in a hospital or DEA registered facility and/or in the presence of another DEA registrant when receiving a controlled substance prescription via telemedicine. This prohibits patients from receiving controlled substance prescriptions via the internet or "skype" in their homes. This requirement has been temporarily waived by the DEA. When this federal waiver ends, patients will have to go to a DEA registered hospital, office or clinic, and be in the presence of a DEA registrant to receive a controlled substance via telemedicine.

Out-of-state practitioners can get a Missouri registration at the physical Missouri address of a registered hospital, office or clinic where the physical exams took place and patient records are maintained.

Practitioners Taking Possession of a Patient's Controlled Substance Prescription

Pharmacies Sending Patient Prescriptions to Practitioners

There has been a change in the statute regarding the ability of practitioners to prescribe a controlled substance and then have a pharmacy deliver the prescription to a practitioner's office.

The Bureau of Narcotics and Dangerous Drugs (BNDD) wishes to clarify what the state and federal law allows. The law does not apply to all controlled substances. Below is a chronological synopsis of the laws:

- US Drug Enforcement Administration (DEA) Regulation 21 CFR 1306.04(b) states that a prescription may not be issued for individual practitioners who intend to create a stock tha will be dispensed to patients. Section 195.010, RSMo defines "dispensing" as prescribing, administering and dispensing and providing drugs to the ultimate user.
- The state of Missouri mirrored this law in Section 195.070.4, RSMo. Through 2019, the Missouri statute stated that no individual practitioner is to accept any portion of a patient's unused controlled substances for any reason. This law changed in 2020 with updates to DEA policies.
- The DEA and Food and Drug Administration determined that there are some controlled drugs that may be safer if they were administered in a practitioner's office. The DEA changed their policy so certain drugs could be accepted by the prescribing practitioner and dispensed in an office setting.
- Qualified practitioners who are authorized to prescribe buprenorphine for the purpose of maintenance or detoxification treatment are authorized to receive a patient's prescription for buprenorphine. That prescribed medication must be in a form that it is administered by injection or implantation.
    - The prescribing by the practitioner and the dispensing by the pharmacy must be in the normal scope of their professional practice.
    - The controlled substances arriving at the practitioner's office may only be administered to the patient named on the prescription, and must be administered no later than 14 days after the date the practitioner received the medication.
    - A prescription still cannot be issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.
    - Practitioners are still required to maintain complete records for these controlled substances such as dates of receipt, charting and administration logs.
- BNDD receives documentation subsequently where the DEA authorizes practitioners to prescribe esketamine nasal spray (Spravato™) and pharmacies may deliver this drug directly to practitioners for administering in their office.
- In 2020, the state of Missouri amended Section 195.070.4, RSMo. That statute now states:

    4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug, except:

        (1) When the controlled substance is delivered to the practitioner to administer to the patient for whom the medication is prescribed as authorized by federal law. Practitioners shall maintain records and secure the medication as required by this chapter and regulations promulgated pursuant to this chapter.

BNDD wants to match the federal DEA with requirements. To avoid changing the statute every time the federal government authorizes a new drug, the current Missouri statute says that practitioners may do this, "as authorized by federal law." So if the DEA allows the drug to be handled this way, the Missouri BNDD will also allow it.

BNDD wanted to provide practitioners and pharmacies with this information to ensure that these practices at this time are only authorized for parenteral buprenorphine products and esketamine nasal spray. The DEA has not authorized any other controlled substances. BNDD surveyed other states for consistency in this and received agreement from the DEA Diversion Program Manager in St. Louis, Mo.

Clarification for Out-of-State Practitioners Prescribing by Telemedicine

The Bureau of Narcotics and Dangerous Drugs (BNDD) is clarifying how out-of-state practitioners may prescribe controlled substances to individuals in Missouri via telemedicine. The bureau has always only issued registrations to practitioners located in Missouri with a physical Missouri practice address. The bureau cannot issue a registration at an out-of-state address pursuant to State Regulation 19 CSR 30-1.019.

- A practitioner must have a Missouri professional license before conducting any activities with controlled substances. (Sections 195.030 and 195.070, RSMo)
- A practitioner must have a Missouri State Controlled Substances Registration from the BNDD before conducting any activities with controlled substances. (Section 195.030, RSMo)
- This Missouri registration must be at a physical Missouri practice location where patient care occurs and controlled substance activities take place. A post office box is not allowed. The BNDD is not authorized to register a practitioner at an out of state address. (19 CSR 30-1.019)
- Before any medicine or treatment may be provided via telemedicine, there must first be a face-to-face, in-person, physical exam as required in Section 334.108, RSMo.

Practitioners who are already physically located in Missouri and have a state drug registration at a Missouri address should not be impacted by this. The patient records would be available for inspection at your primary practice location where patient care occurs.

Out-of-state practitioners not located in Missouri:
You may use the address of the Missouri hospital, office or clinic where the patient went for a physical exam and where the patient charts are located (must be available for copying and inspecting).

Reminder When Over-the-Counter Pseudoephedrine Sales Are Declined

The Bureau of Narcotics and Dangerous Drugs reminds pharmacies of steps to take when the NPLEx pseudoephedrine database declines a sale. The patient may need to make an inquiry as to why their sale was declined. The pharmacy should provide the patient with the declined transaction number and note the date and time. Also provide the patient with the NPLEx customer toll-free number of 888-520-6384, so the patient may make their own inquiry.

Application Information for Resident Physicians and Residency Training Programs

Residency programs start on July 1 each year and run through June 30. In order for first-year residents to get their Missouri Controlled Substances Registration, the Bureau of Narcotics and Dangerous Drugs starts receiving applications as early as April or May each year. These applications are usually incomplete because there is no professional license issued yet. After legal review, the bureau has been informed that we are not authorized to accept and process an incomplete application with no professional license number. The current requirement is for a professional license number to be submitted on each application. First-year residents should not apply for a state controlled drug registration until they have received their medical license. The amended and updated application has been placed on the bureau's website at https://health.mo.gov/safety/bndd.

Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, 3418 Knipp Drive, PO Box 570, Jefferson City, MO 65102; (573) 751-6321; (573) 751-2569 fax; bndd@health.mo.gov; health.mo.gov/safety/bndd/index.php